

PATENT
PC7250AMEB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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IN RE APPLICATION OF: : EXAMINER:
DOUGLAS J. M. ALLEN ET AL. :
CONTINUATION OF: :
SERIAL NO.: 07/449,961 : ART UNIT:
FILED: DECEMBER 21, 1992 :
FOR: AZITHROMYCIN DIHYDRATE :

Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

I hereby certify that this
correspondence is being
deposited with the United States
Postal Service as First Class mail
in an envelope addressed to:
Commissioner of Patents and
Trademarks, Washington, D.C.
20231, on this 28th day of

DECLARATION UNDER 37 C.F.R. § 1.132

By Helen R. Hangac

I, Helen R. Hangac, declare that:

1. I received a Ph.D. degree in Analytical Chemistry
from Duke University in 1982.

2. I have been employed by Pfizer Inc, assignee of
the above-identified application, in the Analytical
Research and Development Department at Groton, Connecticut
since 1982. My current position is that of project leader
in which I am responsible for analytical procedures
performed on experimental pharmaceuticals, including
azithromycin.

3. I am familiar with the subject matter of the
above-identified application.

4. A series of experiments were performed under my
direction by Near Infrared Spectroscopy and X-ray Powder
Diffraction to determine if significant amounts of
azithromycin dihydrate (Type A) were present in
azithromycin (Type B) a hygroscopic monohydrate. The
azithromycin (Type B) lots examined/used in the studies
are listed in Table 1. The azithromycin (Type B) lots
utilized in the experiments were manufactured using three
different crystallizing solvent systems, i.e.,
ethanol/water, acetone/chloroform, and acetone. All lots
of azithromycin (Type B) listed in Table 1 have been shown
to be equivalent using infrared spectrometry, and/or X-ray

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diffraction and are equivalent to the original sample described by Bright in U.S. Patent 4,474,768.

AZITHROMYCIN TYPE B LOTS EXAMINED/USED IN NEAR IR AND X-RAY STUDIES		
LOT NUMBER	TYPE	SOLVENT SYSTEM
1022107	TYPE B	ACETONE/CHLOROFORM
4351080	TYPE B	ACETONE/CHLOROFORM
1039117	TYPE B	ACETONE/CHLOROFORM
4101026	TYPE B	ETHANOL/WATER
13,577-209-1F	TYPE B	ETHANOL/WATER
4101036	TYPE B	ACETONE/CHLOROFORM
17,419-216-3	TYPE B	ACETONE
11,860-18-1 ¹	TYPE B	ETHANOL/WATER
¹ Sample referenced in Bright, U.S. Patent 4,474,768, Example 3.		

5. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

April 19, 1994
Date

Helen H. Hangac
Helen H. Hangac

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